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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/779,457	01/07/1997	PAUL J. CARTER	P0986P2	5894

7590 05/18/2004

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EXAMINER

BELYAVSKIY, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/779,457	Applicant(s) CARTER ET AL.	
	Examiner Michail A Belyavskiy	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11, 12 and 22-29 is/are pending in the application.
- 4a) Of the above claim(s) 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11, 12, 22 and 25-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 03/31/04 is acknowledged.

Claims 1-8, 11-12 and 22-29 are pending.

Claims 23 and 24 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

Claims 1-8, 11, 12, 22 and 25-29 are under consideration in the instant application.

2. The filing date of the instant claims is the filing date of the instant applications, i.e. 01/07/1997, as the previous priority applications 08/667,197 and 08/585,005 do not support the claimed limitations of the instant application, encompassing a method for identifying an antibody recited in claims 1-8, 11,12, 22 and 25-29.

In view of the amendment, filed 03/31/04 the following rejection remains:

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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4. Claims 1-8, 11, 12, 22 and 25-29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US. Patent 5,972,621 in view of Harlow et al (Antibodies, A Laboratory manual, 1988, Cold Spring Harbor) essentially for the same reasons set forth in the previous Office Action, mailed 12/04/03.

Applicant's arguments, filed 03/31/04 have been fully considered, but have not been found convincing.

Applicant asserted that : (i) US Patent '621 does not teach a method for identifying antibodies agonist antibodies that bind to Ob receptor; (ii) US Patent '621 fail to disclose a method for identifying antibodies that decrease body weight and that the passages pointed by the examiner only discuss antibody to ObR generally. However, Applicant acknowledge that US Patent '621 do list agonist and antagonists of ObR i.e. antibodies (see Applicant Response page 5 in particular); (iii) Harlow has no disclosure regarding agonist antibodies. However, Applicant acknowledge that Harlow disclosed antibodies with certain affinities that are used for different purposes (see Applicant Response pages 5 and 6 in particular).

Applicants have traversed the primary and the secondary references pointing to the differences between the claims and the disclosure in each reference. Applicant is respectfully reminded that the rejection is under 35 USC103 and that unobviousness cannot be established by attacking the references individually when the rejection is based on the combination of the references. see In re Keller, 642 F.2d 4B, 208 USPQ 871, 882 (CCPA 1981) See MPEP 2145. This applicant has not done, but rather argues the references individually and not their combination. One cannot show non-obviousness by attacking references individually where the rejections are based on a combination of references. In re Young 403 F.2d 759, 150 USPQ 725 (CCPA 1968). Specific statements in the references themselves which would spell out the claimed invention are not necessary to show obviousness, since questions of obviousness involves not only what references expressly teach, but what they would collectively suggest to one of ordinary skill in the art. See CTS Com. v. Electro Materials Corp. of America 202 USPQ 22 (DC SINY); and In re Burckel 201 USPQ 67 (CCPA).

For examination purposes it is noted that SEQ ID NO:2 of the instant application, coding human receptor variant 13.2 having a WSX motif is 100 % identical to Ob/leptin receptor (ObR) , SEQ ID NO:4 taught by US Patent '621.

Contrary to Applicant's assertion, it is the Examiner position that US Patent '621 teaches a method for identifying antibody which decrease body weight in animals, by specifically binding to extracellular domain of ObR(see entire document, Abstract , column 5, lines 44-60, column 6, lines 50-55 and column 8, lines 22-25 in particular). Moreover, even the title of US Patent '621

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clearly indicated that the invention is drawn to a method of identifying compounds that modulate body weight using the Ob receptor. The examiner does not understand the Applicant's position that "as the list of things that are encompassed by US Patent '621 includes transgenic animals and molecules that act on gene expression it is clear that is not a list of various types of agonists and antagonists". Applicant's attention is drawn to column 5, lines 40-55, wherein it is clearly stated that "the invention also encompasses agonists and antagonists of ObR, including... antibodies". Clearly one skill in the art would immediately understand that US Patent '621 teaches agonistic antibody. The method of identifying antibody comprises producing antibody, testing and identifying antibody that have an ability to decrease body weight (see column 22-23 in particular). US Patent '621 teaches a method of identifying antibodies that can be used in the detection and screening of the ObR in a biological samples, using immunoprecipitation and immunoblotting techniques (see column 22 in particular). US Patent '621 teaches a method for identifying antibody which decrease body weight in obese animals, wherein the obese animal is *ob/ob* mice (column 22, lines 39-48 in particular). US Patent '621 teaches a method for identifying antibody which decrease body weight in obese animals, wherein said antibody specifically bind to human receptor ObR (see column 22, lines 43-45 in particular). US Patent '621 teaches that said antibody is monoclonal or fragment wherein said fragment is F(ab')₂ (column 22, lines 16-25 in particular), or human antibody, or humanized or antibody that also bind to a murine ObR receptor (column 23, lines 12-24 in particular).

US Patent '621 does not teach selecting agonist antibody with a particular affinity with a K_d of no more than 1x10⁻⁷ M.

Harlow et al., teaches that typical affinity values for antibodies used in immunoprecipitation and immunoblotting is in the range between 10⁻⁷ M and 10⁻⁹ M.

It is clear that both the prior art and applicant use the same method for identifying an agonist WSX receptor antibody and use the same treatment to achieve the same results. The claimed binding affinity of no more than about 10⁻⁷ M is within the range between 10⁻⁷ M and 10⁻⁹ M, for antibodies used in immunoprecipitation and immunoblotting as taught by Harlow et al. Thus the referenced antibody taught by US Patent '621 would obviously have binding affinity with a K_d of no more than 1x10⁻⁷ M in the absent a showing of unobvious property. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A.

Claims 4-5 and 7-9 are included because both the reference method of identifying an antibody and the claimed method of identifying an antibody were using the same antigen to produced antibody. Therefore, the reference antibody would obviously bind to receptor having WSX motif within SEQ ID NO2 with same K_d and have the same IC₅₀ in a KIRA ELISA in the absent a showing of unobvious property.

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Claims 10-12 are included because the reference antibodies that specifically binding to extracellular domain of ObR would obviously have biological characteristics of an antibodies of the instant claims.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

5. No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

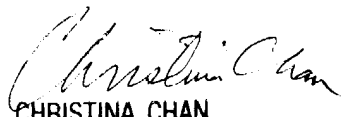
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/ 272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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May 3, 2004


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